Attorney Docket No.: P-4877-US

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

IDDAN, Gavriel J. et al.

Examiner:

FOREMAN, JONATHAN M.

Serial No.:

10/519,918

Group Art Unit:

3736

Filed:

January 3, 2005

Confirmation No.:

2690

Title:

SYSTEM AND METHOD FOR SENSING IN-VIVO STRESS AND

**PRESSURE** 

Mail Stop Amendment Commissioner for Patents P. O. Box 1450 Alexandria, VA 22313-1450

## DECLARATION OF GAVRIEL J. IDDAN UNDER 37 C.F.R. § 1.131

- I, Gavriel J. IDDAN, declare and say as follows:
- 1. I was born in 1941 in Haifa, Israel.
- 2. In 1970, I was awarded the degree of D. Sc. from Technion Israel institution of technology in Haifa, Israel.
- 3. I have been employed by Given Imaging Ltd. ("Given Imaging") of Yoqneam, Israel as full time employee, Until Aug. 2004 and currently hold the position of Chief Technical Officer (full time) at RDC.
- 4. I am aware that the above-identified application was filed in the United States Patent and Trademark Office ("USPTO") on January 3, 2005 as a national phase application under 35 U.S.C. § 371 of International Patent Application No. PCL/IL2003/000559, filed July 3, 2003, which claimed priority from U.S. Provisional Patent Application No. 60/393,300, filed July 3, 2002, and from U.S. Provisional Patent Application No. 60/435,363, filed December 23, 2002. I am one of the inventors of this patent application. I have reviewed and am familiar with this patent application and its disclosures.
- 5. I understand that the USPTO issued a final Office Action on November 28, 2008 wherein the Examiner rejected claims 12, 27 and 40-47 under 35 U.S.C. § 103(a), as being unpatentable over Cho et al. (U.S. Patent Application Publication No. 2004/0106849)

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in view of Kaye et al. (U.S. Patent No. 3,939,823) and Yoon (U.S. Patent No. 6,419,626). I understand that Cho et al. was published on June 3, 2004 but was filed on December 3, 2002.

- 6. I submit this declaration on behalf of Given Imaging under 37 C.F.R. § 1.131 as a declaration of prior invention in support of a Response to Office Action to show that, in accordance with 37 C.F.R. § 1.131, the subject matter of the pending claims of this application was conceived of by the inventors hereof prior to December 3, 2002.
- 7. Attached hereto as Exhibit A are copies of five (5) pages numbered 70-71, 150-51 and 171 from my notebook that reflect contemporaneous thoughts that I had on the days whose dates are written thereon, wherein I described my conception of the elements of this invention as filed in this patent application. Adjacent to a relevant portion of each page is an English language translation of that relevant portion. I state that I am fluent in both the Hebrew and English languages, and I believe that the translated portions of Exhibit A attached hereto are accurate.
- 8. Independent claim 37 as amended in the accompanying Response to Final Office Action recites as follows:
  - 37. A system for collecting and displaying in vivo data, the system comprising:
    a swallowable in vivo imaging device for collecting in vivo images and in
    vivo pressure data, wherein said in vivo device, when swallowed within a patient's
    lumen, has no physical connection to outside of said patient's body, said device
    comprising:
    - a housing including an optical dome, a shell, and a pliant sleeve surrounding said shell, said pliant sleeve defining a space between the shell and the pliant sleeve, said space being filled with a fluid,
    - an imaging system enclosed in said housing behind said optical dome, and
    - a pressure gauge in contact with the fluid in said space between the shell and the pliant sleeve; and
    - a display to display in vivo pressure data provided by said device simultaneously with corresponding in-vivo images provided by the device, wherein said pressure data displayed is measured at a corresponding capture time of the image displayed simultaneously.
- 9. I believe that the subject matter of claim 37 as set forth above was conceived by me and/or other inventors of this application, as recorded in my notes, attached hereto as Exhibit A. Specifically, as made clear by the translated portions of my notes, in discussing a swallowable in vivo imaging device for collecting in vivo images having a housing including

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an optical dome and an imaging system enclosed in said housing behind said optical dome, I conceived:

said in vivo device, when swallowed within a patient's lumen, has no physical connection to outside of said patient's body (diagram, page 71), said device comprising:

a housing including an optical dome, a shell, and a pliant sleeve surrounding said shell, said pliant sleeve defining a space between the shell and the pliant sleeve, said space being filled with a fluid (diagram, page 71; page 171),

a pressure gauge in contact with the fluid in said space between the shell and the pliant sleeve (pages 70-71, 150-51, 170).

It should be noted that pages numbered 70-71, 150-51 and 171 from my notebook in Exhibit A are dated May 22, 2001, January 13, 2002 and February 11, 2002, respectively, all of which dates are prior to December 3, 2002.

I declare under penalty of perjury that all statements made herein are based upon my own knowledge and believed to be true. I understand that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. § 1001), and may jeopardize the validity of any patent that may be issued from the above-identified patent application.

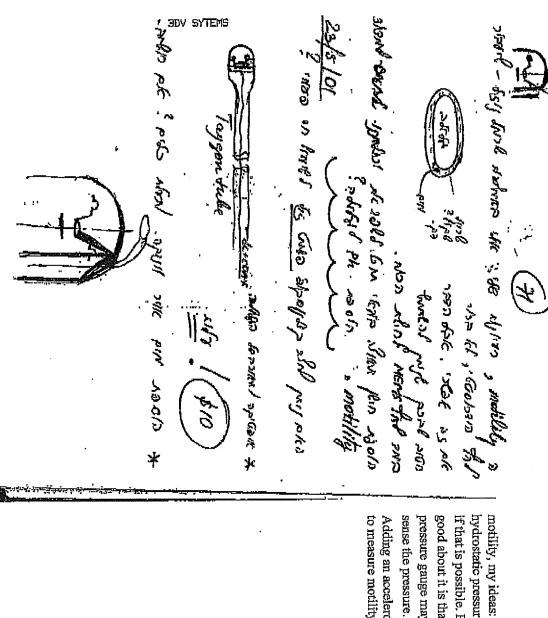
Gavriel J. IDDAN

Date: March 19, 2009

## EXHIBIT A

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A conversation on 22/5/01 [May 22, 2001] with doctors from Mass. General. [They are] interested in adding pressure sensors in the capsule in order to measure the



good about it is that a MEWS if that is possible. But what's pressure gauge may be used to

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to measure motility. Adding pH to the capsule? Adding an accelerometer gauge would surely improve our ability Smert cepsule shelly

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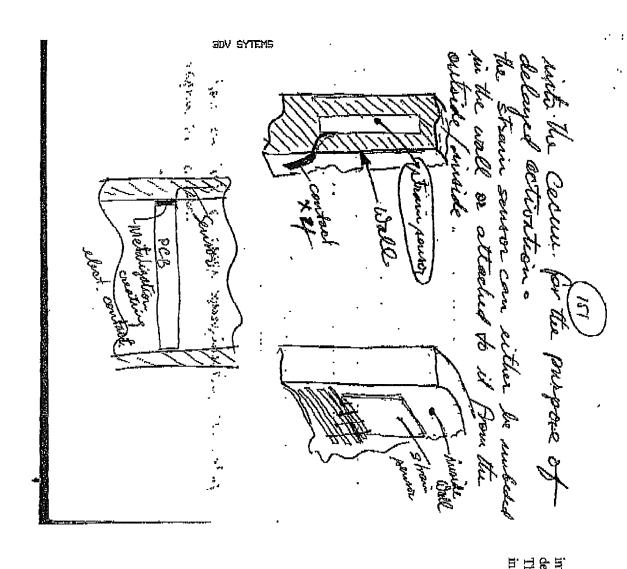
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The

13/01/02 [January 13, 2002]

Smart capsule shell

It is proposed to integrate into the capsule shell some sensors ... such as strain gauges for the purpose of detecting the pressure acting on the capsule's outer shell. Our intension is to use the pressure data to determine the arrival of the capsule



into the cecum for the purpose of delayed activation.

The strain sensor can either be embedded in the wall or attached to it from the outside/inside

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11/02/02:[February 11, 2002]

Measuring pressure in the capsule:-

pressure. The measuring range 10-200mm Hg. assembled on the capsule, and with it we will measure the After a visit to the laboratory of Leuw, I have decided that method similar to the one used to measure blood pressure. the measuring method is not good and we should switch to a That is, Leuw will build a thin latex sleeve which would be

David Leuw, then a Given Imaging employee